



DEPARTMENT OF HEALTH & HUMAN SERVICES

M967N

HFI-35
Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

June 3, 1997

WARNING LETTER
CIM-WL-97-292

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dennis Bolling, CEO
Producers Livestock Association
5909 Cleveland Ave.
P.O. Box 29800
Columbus, Ohio 43229

Dear Mr. Bolling:

Investigation of your Hillsboro and Eaton Animal Auction Markets and Columbus, Ohio headquarters facilities by the Food and Drug Administration revealed sales of veterinary prescription drugs. These sales were made without requiring a written prescription or other order of a licensed veterinarian based upon a valid veterinarian/client/patient relationship. Such sales are a serious violation of Sections 301(a) and 301(k) of the Federal Food, Drug, and Cosmetic Act (the Act).

The drugs Micotil, Nufloor and other veterinary prescription drugs are misbranded while held for sale after shipment in interstate commerce because the labeling of the drugs fails to bear adequate directions for use. The drugs are not exempt from such requirements since they are veterinary drugs, which, because of toxicity or other potentiality harmful effect, or the method of their use, are not safe for use except under the supervision of a licensed veterinarian. The articles fail to comply with the conditions prescribed by Section 503(f)(1) and Title 21, Code of Federal Regulations, Section 201.105 for exemption from Section 502(f)(1) in that the drugs were sold to other than a licensed veterinarian without a valid prescription or other order of a licensed veterinarian based upon a legitimate veterinarian/client/patient relationship. Further your firm does not comply with state law and regulation regarding retail sales of prescription veterinary drugs and therefore does not meet the 21 CFR 201.105(a)(1)(ii) requirement for "lawfully engaged" status.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

The violation listed above is not intended to be all inclusive. You, as a corporate official of this firm have a responsibility to insure that all drugs intended for veterinary use, which bear the veterinary prescription legend "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" are dispensed or sold by your firm on the prescription or other order of a licensed veterinarian based

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upon a valid veterinarian/client/patient relationship. Such sales must also be performed in accordance with state law and regulation regarding sales of prescription veterinary drugs which are described in state law as "Dangerous Drugs".

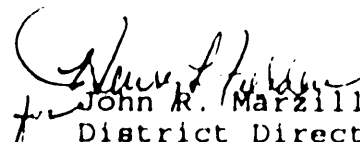
A valid veterinarian/client/patient relationship, as defined by the American Veterinary Medical Association, is the following:

An appropriate veterinarian/client/patient relationship, will exist when: (1) the veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian; and when (2) there is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy.

You are invited to come to the Cincinnati District office at 1141 Central Parkway to present your response to this letter anytime during the 15 working days after receipt of this letter. Your response should include a written statement of the specific steps you have taken to correct the noted violations, including an explanation of each step to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. You should also include copies of any available documentation demonstrating that corrections have been made. This should include a statement of the disposition of the prescription veterinary drugs now in the possession of Producers Livestock Association.

You are invited to call Leonard J. Farr, Compliance Officer at (513) 684-3503 ext. 164 to set a time for the meeting or direct your written response to Mr. Farr at 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,


John R. Marzilli
District Director
Cincinnati District

LJF/clc